UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,074	06/22/2005	Murray James McEwan	15313.0001	9191

27890 7590 08/18/2009

STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER	
SASAKI, SHOGO	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,074	MCEWAN ET AL.	
	Examiner	Art Unit	
	Shogo Sasaki	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/8/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendments to the claims are acknowledged. Filing of 1.132 attribution declaration is also acknowledged.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 1 recites limitation "**amplifying** the amount and rate of ethylene produced in ..." in line 13. There is no specific disclosure of how such step is performed so in the specification. Appropriate correction is required. No new matter should be entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

In claim 1, the omitted steps are for e.g.,: (a) a step for providing reactants (a substrate, an antioxidant and a radical generator); (b) a step for performing a reaction between the reactants to produce a trace volatile in the head space of a reaction mixture; and (c) providing an apparatus for making the measurements. It is unclear if it is intended for the manner in which the radicals and the trace volatile are produced to be a step in the method. Unless a step for creating a chemical (a trace volatile) to be measured and analyzed, the recitation in the preamble would be of a mere purpose of the process. For instance, the first step in claim 1 can be interpreted as "taking in a gas sample," and the last step can be interpreted as "detecting and analyzing the gas sample."

5. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "detecting, amplifying and analyzing the amount and rate of the trace volatile produced in the reaction mixture as a measure of the rate and amount of the natural or synthetic substance, said rate and amount being indicative of the oxidative free radical activities and scavenging activities of the natural or synthetic substance." It is unclear what is used as "a measure of" what activity. It appears that the recitation should be for e.g.: detecting and analyzing the amount and rate of the trace volatile produced in the reaction mixture; creating a data form the detecting and analyzing step; and using the data showing the amount and rate of the trace volatile produced as means to express the oxidative free radical activities and scavenging activities of the natural or synthetic substance.

Claim 3 recites the limitation "the measurement of the rate and amount of the natural or synthetic substance." There is insufficient antecedent basis for this limitation in the claim. It appears that the recitation should be "the amount and rate of the trace volatile produced in the reaction mixture." Appropriate correction is required.

Claim 5 recites the limitation "the concentration of each gas volatile in the gas sample." There is insufficient antecedent basis for this limitation in the claim. Claim 1 only recites a gas volatile of interest.

Claims 5 and 6 recite the limitation "the number densities." There are insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 7 are rejected under 35 U.S.C. 102 as being anticipated by the Applicant's Admission of Prior Art.

Regarding claims 1 and 7, the Applicant's Admission of Prior Art (AAPA) states that the method of the present invention is based on the known partial inhibition of ethylene formation in the presence of antioxidants that compete with KMBA for oxyradicals ([0008]). The AAPA also state that the SIFT-MS technique for analyzing trace components of gas mixtures have been described by Wilson et al. ([0033]). The AAPA further state that the claimed process measures the concentration of ethylene as an assay for antioxidant activity using said SIFT-MS technology ([0009]).

A statement by an applicant in the specification or made during prosecution identifying the work of another as "prior art" is an admission which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 and 7 are rejected under 35 U.S.C. 103 as being unpatentable over by the Applicant's Admission of Prior Art.

Regarding claims 1 and 7, the Applicant's Admission of Prior Art (AAPA) states that the method of the present invention is based on the known partial inhibition of ethylene formation in the presence of antioxidants that compete with KMBA for oxyradicals ([0008]). This has been measured previously in the headspace of a reaction vessel by gas chromatography to derive the Total Oxyradical Scavenging Capacity Assay (id.). The AAPA also state that the SIFT-MS technique for analyzing trace components of gas mixtures have been described by Wilson et al. ([0033]). The AAPA further state that the claimed process measures the concentration of ethylene as an assay for antioxidant activity using said SIFT-MS technology ([0009]). SIFT-MS utilizes selective chemical ionization, using precursor ions generated by electron impact, by microwave discharge or by glow discharge. The precursor ions are mass selected using a quadrupole mass filter to inject mass selected precursor ions into a stream of helium carrier gas and allowed to reach thermal equilibrium ([0034]).

It would have been obvious to one having ordinary skill in the art at the time of the invention to employ mass spectroscopy in place of gas chromatography to detect a trace volatile as taught by AAPA.

The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art; and because "a person of ordinary skill has good reason to pursue the known options within his or her

technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."

A statement by an applicant in the specification or made during prosecution identifying the work of another as "prior art" is an admission which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102.

12. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (Free Radical Biology & Medicine, Vol. 24, No. 3, pp. 480–493, 1998); or Winston et al. (Toxicology and Applied Pharmacology 156, 96-105, 1999) in view of Smith (Med. & Biol. Eng. & Comput., 1996, 34, 409-419); and/or Milligan (J. ENVIRON. QUAL., VOL. 31, MARCH–APRIL 2002).

Regarding claims 1-7, Winston et al. disclose a method of determining, measuring and comparing the oxidative radical activity in a natural or synthetic substance (abstracts), comprising measuring the concentration of ethylene as an assay for antioxidant activity to provide a measurement of the concentration of the analyte to thereby indicate the total activity of an antioxidant and the rate of reaction of the antioxidant with the substrate (abstracts: The chemical species involved in the assay are identical to the ones disclosed in the instant application. Applicant argues that [page 7, second paragraph] Winston uses a different technique to generate the radicals. That is not true. The [0030] of instant application and the "Material and Methods" of Winston are identical as asserted in the previous action. The regents and the experimental conditions such as temperature and pH are the same. The analysis techniques are also the same. See "Quantification of total oxyradial scavenging capacity." The only difference is the measuring equipment employed.).

Although Winston et al. teach the method of assaying the anti-oxidation and scavenging activity of a substance claimed and disclosed by applicant, Winston et al. do not teach the use of mass spectroscopy to detect and analyze the trace volatile from the

head space. Winston et al. employ detection and analysis via gas chromatography to monitor the formation of ethylene in the head space from the reaction vessel (abstract).

The use of mass spectroscopy, specifically SIFT-MS, to measure and analyze a trace volatile over the head space of a gas sample was well know in the art, as evidenced by Smith and Milligan (abstracts). Both teach the advantage of SIFT-MS over the GC, such as omission of pre-concentrating steps and separation; and the possibility of real time measurements (abstract and introduction sections).

Smith and Milligan disclose (entire disclosures):

- producing, mass selecting and accelerating precursor ions into a stream of helium carrier gas, thereby forming an inert carrier gas/ion stream (**Smith**: p410: 2.1, left side of Fig. 1. **Milligan**: p516-518 "Materials and Method");
- injecting the gas sample into the inert carrier gas/ion stream (**Smith**: p410-411, 2.1 and 2.2. **Milligan**: p516-518 "Materials and Method");
- allowing a trace volatile in the gas sample to react with the selected precursor ions thereby forming product ions, wherein the trace volatile in the gas sample reacts with the precursor ions in the inert carrier gas/ion stream (**Smith**: p410-411: 2.1 and 2.2. **Milligan**: p516-518 "Materials and Method");
- detecting, amplifying and analyzing the amount and rate of the trace volatile produced in the reaction mixture (**Smith**: p410-411: 2.1 and 2.2. **Milligan**: p516-518 "Materials and Method");
- wherein the partial pressure of a trace volatile in the gas sample is calculated as part of the measurement (**Smith**: p413, 2.4. **Milligan**: p517, second column);
- wherein the gas sample is introduced into the inert carrier gas/ion stream at a calibrated rate (**Smith**: p411, 2.1 last paragraph; and p411, last paragraph of the left column. **Milligan**: See references to the procedure of Smith) via a heated capillary inlet (**Smith**: p410, 2.1, Fig. 1, inlet port (it would be obvious to heat the inlet for the thermal equilibration with the ion stream or for preventing condensation). **Milligan**: Fig. 1, heated capillary tube);

- wherein the concentration of each trace volatile in the gas mixture sample is calculated from the number densities (**Smith**: p412, first column and p413, 2.4. **Milligan**: p517, second column) of the precursor and product ions; and
- wherein the number densities are measured by a mass filter (**Smith**: p410-411: 2.1 and 2.2, Fig. 1, injection/detection quadrupole mass filter/spectrometer. **Milligan**: Fig. 1, injection/detection quadrupole mass filter/spectrometer {Also see [0034] of instant application. Filter means of instant application; and Smith or Milligan are equivalent.}) in conjunction with a particle multiplier and a software interface (**Smith**: a particle multiplier is a part of mass spectrometer, and a mass spectrometer will have to be provided with a computer interface, p414 2.5. **Milligan**: Fig. 1, and p518 "Data Acquisition").

It would have been obvious to one having ordinary skill in the art at the time of the invention to employ mass spectroscopy in place of gas chromatography to detect a trace volatile as taught by Smith and Milligan.

The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art; and because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."

Response to Arguments

13. The objection to claim 1 from the last office action is withdrawn.

14. The objection to the specification is maintained. The objection was for the recitation "amplifying..." The recitation "detecting" and "analyzing" are shown in the disclosure as applicant sated in the reply. Applicant also argues that the passage "***Modifications of the SIFT-MS technique for analyzing trace components of gas mixtures have been described*** *by Milligan D B, Wilson P F, Mautner M N, Freeman C G, McEwan M J, Clough T J, Sherlock R R. Real-Time, High-Resolution Quantitative Measurement of Multiple Soil Gas Emissions: Selected Ion Flow Tube Mass*

Spectrometry. J. Environ. Qual. 2002 31: 515-524. SIFT-MS measures trace gases in complex mixtures such as air, breath and the headspace above liquids, allowing the analysis of a single exhalation of breath in real time, giving immediate results without the need for pre-concentration of the volatile gas compounds or calibration using standards" proves that skilled artisan would understand the recited step. The passage states that the techniques have been previously described. Did applicant mean that the step was well known in the art?

15. It is noted that substantial changes were made to the claims. The 112 (2) rejections from the last office action are fully withdrawn. However, claims 1-7 are newly rejected under 112 (2) for different reasons (See paragraphs 3-5).

16. The attribution declaration under 37 CFR 1.132 filed 4/08/2009 is sufficient to overcome the rejections of claim 1-6 based upon 103(a). However it is requested that applicant file a supplementary document showing the inventorship of the provisional application NZ 520019 to perfect the foreign priority claim.

17. Applicant's arguments with respect to the prior art rejection of the original claims 1-6, have been considered but they are not persuasive. (See new rejection in paragraph 12. The ground of the rejection has changed. However the rationales for the rejection are substantially the same. Therefore, examiner's responses to applicant remarks have been included in the new rejection.)

18. In the reply in the remark section, it is requested that applicant provide an explanation regarding how the table (TOSCA-SIFT vs. TOSCA-GC) in [0039] should be interpreted. Is applicant showing the unexpected improvement of SIFT technique over GC? The ranges of numbers appear to be very similar.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS
8/13/2009

/Brian R Gordon/
Primary Examiner, Art Unit 1797